

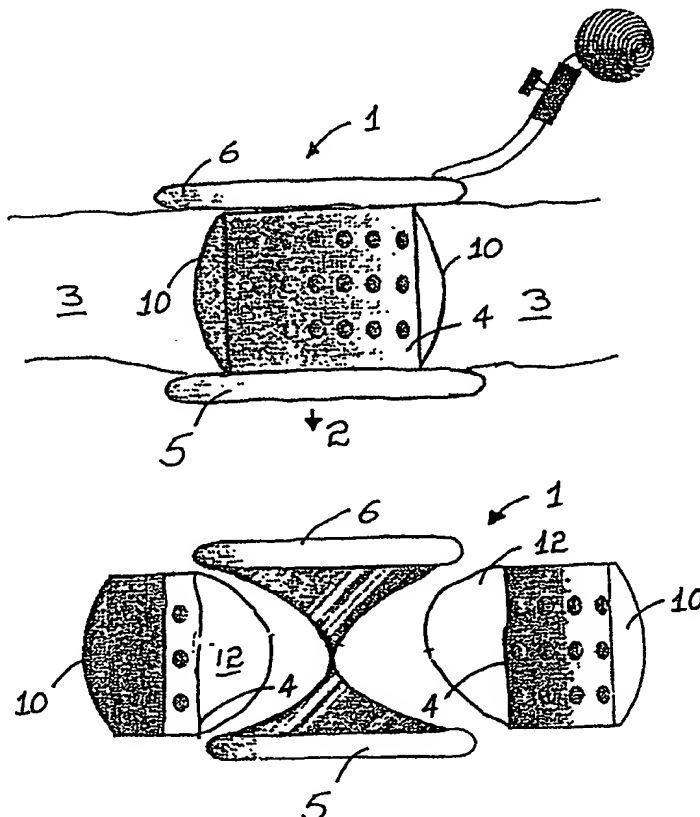


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/34	A1	(11) International Publication Number: WO 00/54675 (43) International Publication Date: 21 September 2000 (21.09.00)
(21) International Application Number: PCT/IE00/00032 (22) International Filing Date: 20 March 2000 (20.03.00) (30) Priority Data: S990219 18 March 1999 (18.03.99) IE (71) Applicant (for all designated States except US): GAYA LIMITED [IE/IE]; 2-3 Sandyford Village, Sandyford, Dublin 18 (IE). (72) Inventors; and (75) Inventors/Applicants (for US only): CALDWELL, Martin [IE/IE]; 37 Mount Pleasant Square, Ranelagh, Dublin 6 (IE). MUNTNER, Mike [IE/IE]; 19 Doonamana Road, Dun Laoire, County Dublin (IE). (74) Agent: MACLACHLAN & DONALDSON; 47 Merrion Square, Dublin 2 (IE).		(81) Designated States: CA, CN, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: A SURGICAL ACCESS DEVICE**(57) Abstract**

Surgical device (1) is for use in minimally invasive surgery using an inflated body cavity (2) accessible to a surgeon through an access port defined by a sleeve (4) passing through an incision in a patient's abdominal wall (3). The device is held in position by a distal ring (5) and a proximal ring (6). An incision engaging bladder (10) provides a first seal for engaging and retracting the incision when inflated. A second seal is provided by a self engaging bladder (12) for sealing the sleeve (4).



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A SURGICAL ACCESS DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

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Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

10 A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate

15 using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may

20 interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

25 A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patients abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

30

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

5

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

10

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

15

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Ideally, the sleeve is provided by a perforated wall defining a substantially cylindrical tube.

20

Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

Preferably, the fixing means is provided by a proximal ring for engaging with a patient's skin.

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In one arrangement, the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

30

In a preferred arrangement, the sealing means is provided by an inflatable first seal for engaging and retracting the incision and a second inflatable seal for sealing the lumen of the tube or sleeve bore.

Ideally, the first seal is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision.

- 5 Preferably, the second seal is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation to prevent excessive loss of gas through the access port.

In a particularly preferred arrangement, the second seal is operatively connected and mounted within the first seal.

10

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, an embodiment of a surgical device in accordance with the invention, in which:-

- 15 Fig. 1 is a front view of a surgical device in accordance with the invention; and

Fig. 2 is an exploded view of the surgical device of Fig. 1.

- Referring to the drawings, there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, passing through an incision in a patient's abdominal wall 3. The sleeve 4 is provided in this case by a perforated wall defining a cylindrical tube

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- In more detail, the device 1 has a body cavity engagement means provided by a distal ring 5 for insertion into the incision to locate the device 1 in position. The device 1 is held in position on the patient's skin outside the body by a fixing means provided in this case by a proximal ring 6. The distal ring 5 and proximal ring 6 ensure that the device 1 is securely fixed in position, both rings 5,6 surround the incision and the sleeve 4 passes through the incision connecting the rings.
- 30

The proximal ring 6 may have a connector ring (not shown) for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring may also be used for holding or guiding medical instruments into position over, through or in the incision.

- 5 Sealing means is provided to prevent undue loss of gas from the inflated body cavity 2 by a two part inflatable seal. An incision-engaging bladder 10 provides a first seal for engaging and retracting the incision when inflated. A second seal is provided by a self-engaging bladder 12 mounted within the sleeve 4 for sealing the sleeve 4 when similarly inflated. The sleeve 4 separates the incision-engaging bladder 10 and the self-engaging bladder 12.
- 10 The self-engaging bladder 12 surrounds the internal surface of the sleeve 4 and the external surface of the sleeve 4 is in turn surrounded by the incision-engaging bladder 10 thereby providing a compact unit, which is easy to operate.

- In use, an incision is made in the abdominal wall 3 and the distal ring 5 passed through the
- 15 incision into the cavity 2. The distal ring 5 is moved when in the cavity 2 so that the ring 5 surrounds the incision. The proximal ring 6 is then attached to the patients skin to fix the device 1 in position with the sleeve 4 being connected between the proximal ring 6 and the distal ring 5 and passing between the portions of the abdominal wall 3 exposed by the incision. The incision-engaging bladder 10 and the self-engaging bladder 12 both
- 20 surrounding the sleeve 4 are also in position passing through the abdominal wall. A hand operated bellows 11 can then pumped to inflate both the incision-engaging bladder 10 and the self-engaging bladder 12. The incision-engaging bladder 10 expands outwardly from the external wall of the sleeve 4 to press against the abdominal wall exposed by the incision to prevent loss of gas from the cavity 2. The self-engaging bladder 12 expands
- 25 inwardly from the internal wall of the sleeve 4 to close the sleeve 4 against itself thereby preventing loss of gas through the sleeve 4.

- When a surgeon wishes to gain access to the cavity 2 a hand or instrument is passed down through the sleeve 4. The inward pressure of the self-engaging bladder 12 ensures that the
- 30 sleeve is only opened sufficiently to allow the inserted object to pass but prevents loss of pressure from the body cavity. As the object is removed, the same pressure re-seals the sleeve 4 as described above. As a hand or instrument is passed down through the sleeve 4,

air or gas is expelled from the bladder 12 through perforations in the sleeve 4. The expelled air or gas is forced into the bladder 10 which expands and further retracts the incision, enhancing the ease of access through the sleeve 4 and incision.

- 5 It will be noted that while a bellows or inflating device is described, with air or gas communicating between the incision-engaging bladder and the sleeve-engaging bladder it is anticipated that separate inflation devices for independent control may be used.

- 10 It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device,

5 surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

10 fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

15 sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

20 2. A surgical device as claimed in Claim 1, in which the sleeve is provided by a perforated wall defining a substantially cylindrical tube.

3. A surgical device as claimed in Claim 1 or Claim 2, in which the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

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4. A surgical device as claimed in any one of the preceding claims, in which the fixing means is provided by a proximal ring for engaging with a patient's skin.

5. A surgical device as claimed in Claim 4, in which the proximal ring has an associated
30 connector ring for receiving additional seals or medical instruments.

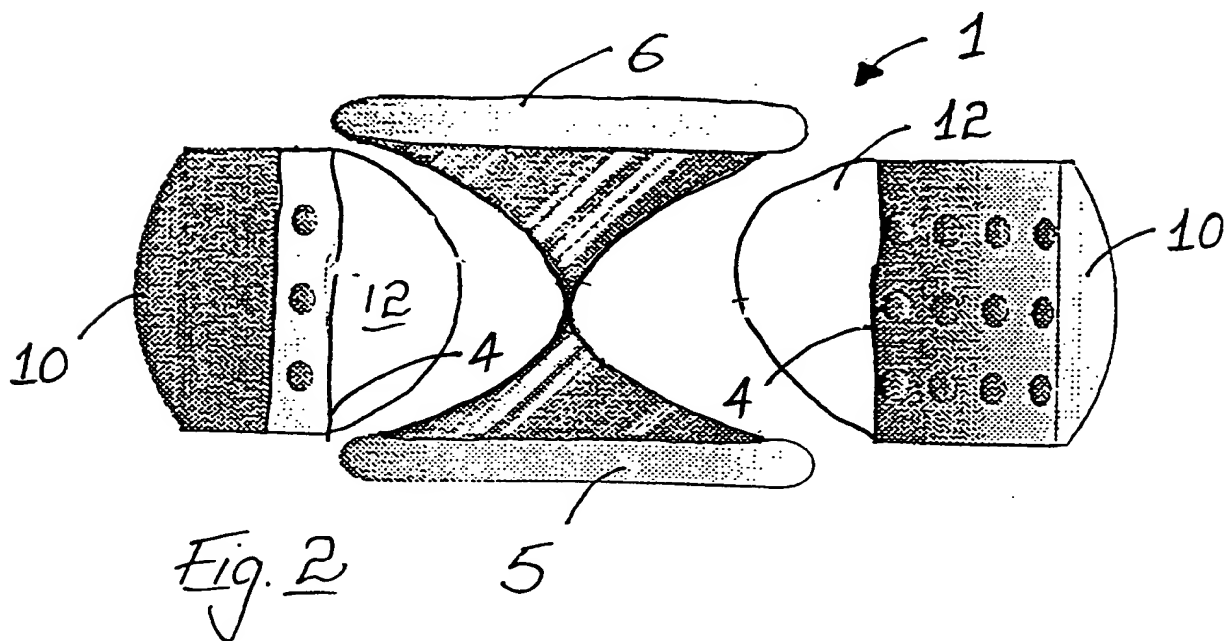
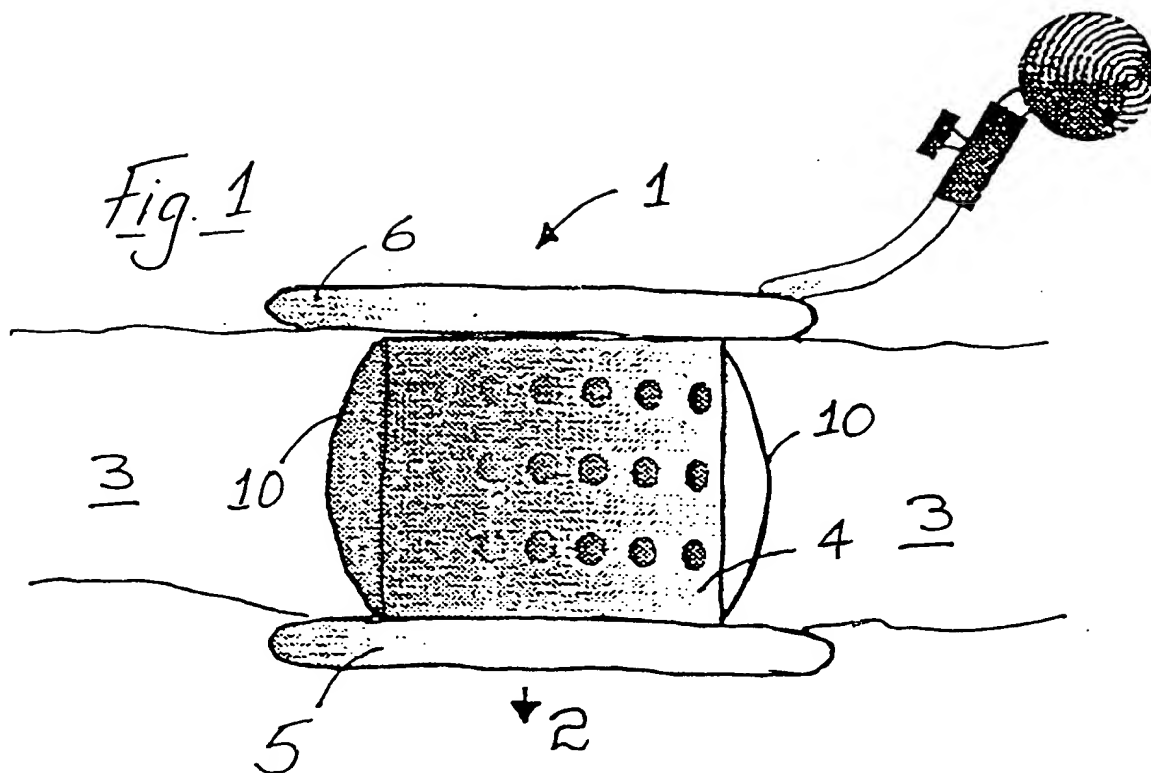
6. A surgical device as claimed in any one of the preceding claims in which the sealing means is provided by an inflatable first seal for engaging and retracting the incision and a second inflatable seal for sealing the lumen of the tube or sleeve bore.

5 7. A surgical device as claimed in Claim 6, in which the first seal is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision.

8. A surgical device as claimed in Claim 6 or Claim 7, in which the second seal is
10 provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation to prevent excessive loss of gas through the access port.

9. A surgical device as claimed in Claim 8, in which the second seal is operatively connected and mounted within the first seal.

1/1



INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00032

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 36283 A (GEN SURGICAL INNOVATIONS INC) 21 November 1996 (1996-11-21)	1,2
Y	page 13, line 19 -page 15, line 15; figure 12	3-5
X	US 5 366 478 A (CANDADAI RAMESH S ET AL) 22 November 1994 (1994-11-22)	1,3-5
Y	abstract; figures 1,2	3-5
X	GB 2 275 420 A (GAUNT) 31 August 1994 (1994-08-31)	1
	abstract; figures 3,10	
A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21)	5
	column 8, line 61 - line 67; figure 2	
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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A document member of the same patent family

Date of the actual completion of the international search

14 July 2000

Date of mailing of the international search report

21/07/2000

Name and mailing address of the ISA

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Authorized officer

Moers, R

INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/IE 00/00032

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 95 07056 A (ENCORET) 16 March 1995 (1995-03-16) cited in the application abstract; figure 9</p>	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l. Application No

PCT/IE 00/00032

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9636283	A	21-11-1996	US 5634937 A US 5964781 A	03-06-1997 12-10-1999
US 5366478	A	22-11-1994	NONE	
GB 2275420	A	31-08-1994	NONE	
US 5741298	A	21-04-1998	US 5947922 A	07-09-1999
WO 9507056	A	16-03-1995	AT 188364 T AU 696289 B AU 7507494 A CA 2171177 A DE 69422530 D EP 0776180 A EP 0834279 A EP 0888755 A EP 0887047 A EP 0887048 A ES 2142404 T JP 9502624 T	15-01-2000 03-09-1998 27-03-1995 16-03-1995 10-02-2000 04-06-1997 08-04-1998 07-01-1999 30-12-1998 30-12-1998 16-04-2000 18-03-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00032

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9636283	A	21-11-1996	US 5634937 A		03-06-1997
			US 5964781 A		12-10-1999

US 5366478	A	22-11-1994	NONE		

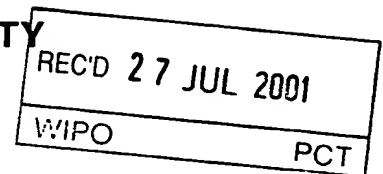
GB 2275420	A	31-08-1994	NONE		

US 5741298	A	21-04-1998	US 5947922 A		07-09-1999

WO 9507056	A	16-03-1995	AT 188364 T		15-01-2000
			AU 696289 B		03-09-1998
			AU 7507494 A		27-03-1995
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			DE 69422530 D		10-02-2000
			EP 0776180 A		04-06-1997
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			EP 0887048 A		30-12-1998
			ES 2142404 T		16-04-2000
			JP 9502624 T		18-03-1997

PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P7964.WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IE00/00032	International filing date (day/month/year) 20/03/2000	Priority date (day/month/year) 18/03/1999
International Patent Classification (IPC) or national classification and IPC A61B17/34		
Applicant GAYA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 11/09/2000	Date of completion of this report 26.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Moers, R Telephone No. +31 70 340 2375 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00032

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

3-5	as originally filed			
1,2	as received on	20/02/2001	with letter of	15/02/2001

Claims, No.:

1-8	as received on	20/02/2001	with letter of	15/02/2001
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Drawings, sheets:

1/1	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IE00/00032

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

WO-A-9636283 (D1) discloses (see Fig. 12) a surgical access device comprising distal body cavity engagement means, proximal fixing means and an interconnecting sleeve 48 defining an access port. The sleeve has an inflatable inner seal for sealing the lumen of the sleeve.

The technical problem is how to improve the sealing capabilities of such a device. The solution is to provide the interconnecting sleeve with a first outer inflatable seal and a second inner inflatable seal, making it better adjustable for sealing both sides of the sleeve.

Access ports with inner and outer inflatable seals are known in the prior art (see D1, Fig. 17 and US-A-5366478 (D2), Fig. 1) but these consist of one single dumbbell shaped balloon, not connected to a sleeve (D2) or connected at one side only (D1).

531 Rec'd PCT/TE00/00032
A SURGICAL ACCESS DEVICE

18 SEP 2001

REPLACED BY
ART 34 AMDT

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patient's abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

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body cavity engagement means for insertion into the incision to locate the device in position;

10

fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

15

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

20

Ideally, the sleeve is provided by a perforated wall defining a substantially cylindrical tube.

Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

25

Preferably, the fixing means is provided by a proximal ring for engaging with a patient's skin.

In one arrangement, the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

30

In a preferred arrangement, the sealing means is provided by an inflatable first seal for engaging and retracting the incision and a second inflatable seal for sealing the lumen of the tube or sleeve bore.

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device,
5 surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

10 fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

15 sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

- 20 2. A surgical device as claimed in Claim 1, in which the sleeve is provided by a perforated wall defining a substantially cylindrical tube.

3. A surgical device as claimed in Claim 1 or Claim 2, in which the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

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4. A surgical device as claimed in any one of the preceding claims, in which the fixing means is provided by a proximal ring for engaging with a patient's skin.

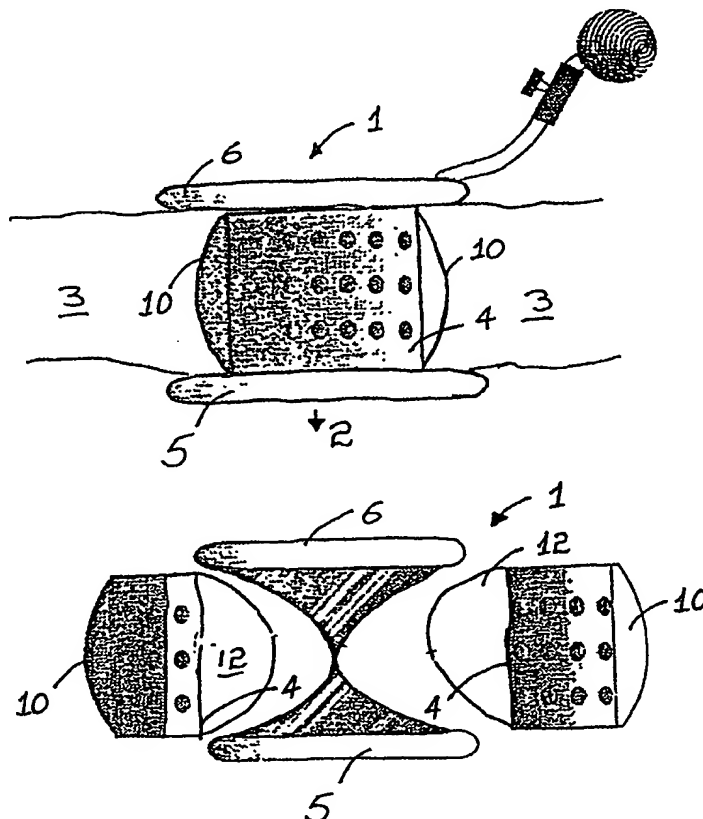
5. A surgical device as claimed in Claim 4, in which the proximal ring has an associated
30 connector ring for receiving additional seals or medical instruments.

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/34	A1	(11) International Publication Number: WO 00/54675 (43) International Publication Date: 21 September 2000 (21.09.00)
(21) International Application Number: PCT/IE00/00032 (22) International Filing Date: 20 March 2000 (20.03.00) (30) Priority Data: S990219 18 March 1999 (18.03.99) IE (71) Applicant (for all designated States except US): GAYA LIMITED [IE/IE]; 2-3 Sandyford Village, Sandyford, Dublin 18 (IE). (72) Inventors; and (75) Inventors/Applicants (for US only): CALDWELL, Martin [IE/IE]; 37 Mount Pleasant Square, Ranelagh, Dublin 6 (IE). MUNTNER, Mike [IE/IE]; 19 Doonamana Road, Dun Laoire, County Dublin (IE). (74) Agent: MACLACHLAN & DONALDSON; 47 Merrion Square, Dublin 2 (IE).		(81) Designated States: CA, CN, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: A SURGICAL ACCESS DEVICE**(57) Abstract**

Surgical device (1) is for use in minimally invasive surgery using an inflated body cavity (2) accessible to a surgeon through an access port defined by a sleeve (4) passing through an incision in a patient's abdominal wall (3). The device is held in position by a distal ring (5) and a proximal ring (6). An incision engaging bladder (10) provides a first seal for engaging and retracting the incision when inflated. A second seal is provided by a self engaging bladder (12) for sealing the sleeve (4).



PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P7964.W0	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IE 00/00032	International filing date (day/month/year) 20/03/2000	(Earliest) Priority Date (day/month/year) 18/03/1999
Applicant GAYA LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

A SURGICAL ACCESS DEVICE

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1,2

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00032

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 36283 A (GEN SURGICAL INNOVATIONS INC) 21 November 1996 (1996-11-21)	1,2
Y	page 13, line 19 -page 15, line 15; figure 12	3-5
X	US 5 366 478 A (CANDADAI RAMESH S ET AL) 22 November 1994 (1994-11-22)	1,3-5
Y	abstract; figures 1,2	3-5
X	GB 2 275 420 A (GAUNT) 31 August 1994 (1994-08-31)	1
	abstract; figures 3,10	
A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21)	5
	column 8, line 61 - line 67; figure 2	
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 2000

Date of mailing of the international search report

21/07/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Moers, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00032

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 95 07056 A (ENCORET) 16 March 1995 (1995-03-16) cited in the application abstract; figure 9</p> <p style="text-align: center;">-----</p>	1

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P7964.WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IE00/00032	International filing date (day/month/year) 20/03/2000	Priority date (day/month/year) 18/03/1999
International Patent Classification (IPC) or national classification and IPC A61B17/34		
Applicant GAYA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 11/09/2000	Date of completion of this report 26.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Moers, R Telephone No. +31 70 340 2375 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00032

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

3-5 as originally filed

1,2 as received on 20/02/2001 with letter of 15/02/2001

Claims, No.:

1-8 as received on 20/02/2001 with letter of 15/02/2001

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IE00/00032

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-8
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-8
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IE00/00032

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

WO-A-9636283 (D1) discloses (see Fig. 12) a surgical access device comprising distal body cavity engagement means, proximal fixing means and an interconnecting sleeve 48 defining an access port. The sleeve has an inflatable inner seal for sealing the lumen of the sleeve.

The technical problem is how to improve the sealing capabilities of such a device. The solution is to provide the interconnecting sleeve with a first outer inflatable seal and a second inner inflatable seal, making it better adjustable for sealing both sides of the sleeve.

Access ports with inner and outer inflatable seals are known in the prior art (see D1, Fig. 17 and US-A-5366478 (D2), Fig. 1) but these consist of one single dumbbell shaped balloon, not connected to a sleeve (D2) or connected at one side only (D1).

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A SURGICAL ACCESS DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

5

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

10 A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate

15 using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may

20 interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

25 A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patients abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

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International Patent Specification No. WO 96/36283 discloses surgical access devices for sealing an incision and providing a sealed access port for surgical instruments. In one

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embodiment disclosed in the specification of WO 96/36283, a flexible skin seal is fitted with one or more dumb-bell shaped balloons. These balloons can be inflated after the skin seal is inserted into an incision in the abdomen.

- 5 There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port,
10 defined by the device, surrounding an incision in a patient's body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position; fixing means for attaching the device to a patients skin; a sleeve connected between the body cavity engagement means and the fixing means
15 defining an access port; and characterized in that the device includes sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position, the sealing means being provided by an inflatable first seal for engaging
20 and retracting the incision and a second inflatable seal for sealing the lumen of the tube or sleeve bore.

Ideally, the sleeve is provided by a perforated wall defining a substantially cylindrical tube.

- 25 Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

Preferably, the fixing means is provided by a proximal ring for engaging with a patient's skin.

- 30 In one arrangement, the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

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CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type using an inflated body cavity (2) accessible to a surgeon through an access port, defined by the device (1), surrounding an incision in a patient's body, the device having: -

body cavity engagement means (5) for insertion into the incision to locate the device in position;

fixing means (6) for attaching the device to a patients skin;

a sleeve (4) connected between the body cavity engagement means (5) and the fixing means defining an access port; and

characterized in that the device includes sealing means (10, 12), operating on the sleeve (4) to prevent substantial leakage of gas from the body cavity (2) on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position, the sealing means being provided by an inflatable first seal (10) for engaging and retracting the incision and a second inflatable seal (12) for sealing the lumen of the tube or sleeve bore.

2. A surgical device (1) as claimed in Claim 1, in which the sleeve (4) is provided by a perforated wall defining a substantially cylindrical tube.

3. A surgical device (1) as claimed in Claim 1 or Claim 2, in which the body cavity engagement (5) means is provided by a distal ring (5) formed for insertion into the incision.

4. A surgical device (1) as claimed in any one of the preceding claims, in which the fixing means (6) is provided by a proximal ring (6) for engaging with a patient's skin.

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5. A surgical device (1) as claimed in Claim 4, in which the proximal ring (6) has an associated connector ring for receiving additional seals or medical instruments.
6. A surgical device as claimed in any one of the preceding claims, in which the first seal (10) is provided by an inflatable bladder (10) extending outwardly from the sleeve on inflation to form a seal with the incision.
7. A surgical device as claimed in any one of the preceding claims, in which the second seal (12) is provided by an inflatable bladder (12) extending inwardly from the tube or sleeve (4) on inflation to prevent excessive loss of gas through the access port.
8. A surgical device as claimed in Claim 7, in which the second seal (12) is operatively connected and mounted within the first seal (10).

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Creation date: 09-18-2004
Indexing Officer: SWOLDEYSUS - SAMUEL WOLDEYSUS
Team: OIPEBackFileIndexing
Dossier: 09936723

Legal Date: 01-17-2002

No.	Doccode	Number of pages
1	M905	2

Total number of pages: 2

Remarks:

Order of re-scan issued on